

6. TROUBLESHOOTING

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OVERVIEW

This section provides a Troubleshooting Chart designed to help identify the cause of a particular symptom or problem during ventilator operation and to provide recommended corrective actions.

Most of the recommended corrective actions can be performed by the operator.

WARNING

If the problem cannot be corrected as outlined in the Troubleshooting Chart, an internal malfunction may exist. In this case, refer the ventilator to an authorized Allied service technician. **DO NOT** use on a patient.

ALARM STATE

An ALARM STATE occurs when a failure results in a reduced level of ventilator performance which does not cause harm to the patient. When an ALARM STATE exists, the following events occur:

- The RUN DIAGNOSTICS audible and visual alarm activate.
- Specific clinician-adjustable alarms may activate.
- A Troubleshooting Code identifying the specific failure is recorded in the ventilator's memory (this code can be retrieved by pressing the TEST key to display the code in the TOTAL MINUTE VOLUME alarm LED).
- The ventilator continues to operate.

DEFAULT STATE

The setting EEPROM (SE²) stores all ventilator settings during power-down. If a SE² checksum error is encountered during power-up, the following occurs:

- Run Diagnostics Audible and Visual alarms.
- dEF is displayed in the Minute Volume Alarm window.
- The alarm is silenceable but not resettable until at least one (1) setting is changed.
- Ventilator resorts to the following settings:

DEFAULT SETTINGS

Basic Controls

Tidal Volume	0.10L	Breath Rate	0 BPM
Peak Flow	10 LPM	% Oxygen	100%
Pressure Support	0 cmH ₂ O	Assist Sensitivity	1.0 cmH ₂ O
Inspiratory Pause	0.0 sec	MMV Level	0 LPM
Compliance Comp	0.0 ml/cm H ₂ O	Inspiratory Time	0.1 sec
Inspiratory Pressure	0 cmH ₂ O	Base Flow	0 LPM
Pressure Slope	0	PEEP/CPAP	0.0 cmH ₂ O
Mode	SIMV/CPAP	Waveform	Square
100% Oxygen	Off	Sighs	Off
Pressure Augment	Off	Nebulizer	Off

Alarm Settings

I:E Override	Off	High Total Minute Volume	80 LPM
Low Total Minute Volume	0 LPM	High Total Minute Volume	155 BPM
Low Total Breath Rate	3 BPM	High Peak Insp Pressure	120 cmH ₂ O
Low Peak Insp Pressure	3 cmH ₂ O	High Baseline Pressure	55 cmH ₂ O
Low Baseline Pressure	0 cmH ₂ O	Barometric Pressure	14.2 psig

FAIL STATE

A FAIL STATE occurs when a failure greatly impairs ventilator performance. In this event the following occurs:

- The FAILED TO CYCLE alarm lights and sounds an audible alarm until the power is turned off.
- A Troubleshooting Code identifying the specific failure is recorded in memory (and can be retrieved by pressing the TEST key).
- The SOPR valve opens and allows the patient to breathe spontaneously through the patient circuit.
- An audible alarm sounds for at least five minutes, even if the cause of the FAILED TO CYCLE alarm is a power failure.

WARNING

A FAILED TO CYCLE alarm is accompanied by a loss of mechanical ventilation including loss of PEEP.
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Chart 6A • Troubleshooting Symptoms and Corrective Actions

SYMPTOM	INDICATED BY	POSSIBLE CAUSES	CORRECTIVE ACTION																								
Ventilator continues operating with a RUN DIAGNOSTICS Alarm	RUN DIAGNOSTICS Alarm		When alarm is activated, ventilation continues. After the patient is removed from the ventilator, refer the unit to an authorized service technician.																								
		<table><tr><th>Code</th><th>Type of Failure</th></tr><tr><td>dEF</td><td>Saved Settings Fault</td></tr><tr><td>E25</td><td>Configuration Fault</td></tr><tr><td>E32</td><td>Fan Fault</td></tr><tr><td>E33</td><td>Oxygen Blender Fault</td></tr><tr><td>E34</td><td>Flow Sensor Fault</td></tr><tr><td>E35</td><td>Flow Sensor PCB</td></tr><tr><td>E36</td><td>FCV Fault</td></tr></table>	Code	Type of Failure	dEF	Saved Settings Fault	E25	Configuration Fault	E32	Fan Fault	E33	Oxygen Blender Fault	E34	Flow Sensor Fault	E35	Flow Sensor PCB	E36	FCV Fault	Replace flow sensor								
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E36	FCV Fault																										
Ventilator fails to cycle	FAILED TO CYCLE Alarm		Remove the patient from the ventilator. Provide alternate ventilation and refer the unit to an authorized service technician.																								
		<table><tr><th>Code</th><th>Type of Failure</th></tr><tr><td>E1-E9</td><td>Control PCB Fault</td></tr><tr><td>E10-E15</td><td>EPI PCB Fault</td></tr><tr><td>E20-E23</td><td>Monitor PCB Fault</td></tr><tr><td>E31</td><td>Solenoid Fault</td></tr><tr><td>E37</td><td>FCV Fault</td></tr><tr><td>E38</td><td>A/D Converter Fault</td></tr><tr><td>E39</td><td>"Low line" power fault (check external power supplied to ventilator)</td></tr><tr><td>E40</td><td>Flow Sensor auto zero error</td></tr><tr><td>E42</td><td>Brown-out was detected (check external power supplied to ventilator)</td></tr><tr><td>E43</td><td>Internal power supply fault</td></tr><tr><td>E44</td><td>"High Line" power fault (check external power supplied to ventilator)</td></tr><tr><td>E45-E51</td><td>Communication fault</td></tr></table>	Code	Type of Failure	E1-E9	Control PCB Fault	E10-E15	EPI PCB Fault	E20-E23	Monitor PCB Fault	E31	Solenoid Fault	E37	FCV Fault	E38	A/D Converter Fault	E39	"Low line" power fault (check external power supplied to ventilator)	E40	Flow Sensor auto zero error	E42	Brown-out was detected (check external power supplied to ventilator)	E43	Internal power supply fault	E44	"High Line" power fault (check external power supplied to ventilator)	E45-E51
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SYMPTOM	INDICATED BY	POSSIBLE CAUSES	CORRECTIVE ACTION
Inspiratory time not including Inspiratory pause exceeds 5 seconds for any breath type.	TIME/I:E LIMIT Alarm	1. Incompatible or improperly set TIDAL VOLUME, RATE, PEAK FLOW, and INSPIRATORY PAUSE settings.	1. Re-evaluate TIDAL VOLUME, RATE, PEAK FLOW, WAVEFORM and INSPIRATORY PAUSE settings.
I:E ratio is being limited to 1:1.	TIME/I:E LIMIT Alarm	2. I:E OVERRIDE key is not activated if inverse I:E ratio is desired.	2. Activate I:E OVERRIDE key to override 1:1 limit.
Ventilator operates with Audible alarm sounding and "brn" displayed in Total Minute Volume window	"brn" displayed in Total Minute Volume window and continuous Audible Alarm active.	1. A loss of power was experienced, an E-42 indicates a "Brown-Out" was detected.	1. Verify external power supply to the ventilator is reliable.
High Total Minute Volume	High TOTAL MINUTE VOLUME Alarm	1. Change in patient status: increase in spontaneous volume or rate. 2. Patient may be supplementing tidal volume with volume augmentation. 3. Auto-cycling for any reason.	1. Re-evaluate patient and alarm setting. 2. Reassess TIDAL VOLUME and PEAK FLOW settings. Re-evaluate alarm setting. 3. Re-evaluate Assist Sensitivity setting.

SYMPTOM	INDICATED BY	POSSIBLE CAUSES	CORRECTIVE ACTION
Low Total Minute Volume	Low TOTAL MINUTE VOLUME Alarm	1. Leaks in the patient circuit and/or humidification system. 2. Patient disconnect. 3. Leak in exhalation valve diaphragm and/or condensate jar. 4. External flow sensor not properly connected to Exhalation Valve. 5. Improperly set alarm; may be set too high. 6. Change in patient' status; decrease in spontaneous volume or rate; patient air leak.	1. Check for patient circuit leaks. Ensure humidifier chamber is secure. 2. Reconnect the patient. 3. Perform leak test (Section 7) and replace diaphragm if leaking or damaged. Visually inspect jar for seam cracks and misthreadings. 4. Check for secure connection. 5. Re-evaluate alarm. 6. Re-evaluate patient and control settings.
	"FLO" alarm	1. External flow sensor not properly connected to Exhalation Valve.	1. Check for secure connection.
	Low TOTAL MINUTE VOLUME Alarm accompanied by: RUN DIAGNOSTICS Alarm.	1. Disconnect of External Flow Sensor 2. Defective External Flow Sensor	1. Reconnect External Flow Sensor. 2. Replace External Flow Sensor.

SYMPTOM	INDICATED BY	POSSIBLE CAUSES	CORRECTIVE ACTION
High Total Breath Rate	High TOTAL BREATH RATE Alarm	1. Change in patient status; increase in patient breath rate. 2. Improperly set alarm. 3. Improper adjustment of ASSIST SENSITIVITY; autocycling due to leaks.	1. Re-evaluate patient status, control settings (including PRESSURE SLOPE) and alarm setting. 2. Re-evaluate alarm setting. 3. Check for patient circuit leaks. Re-evaluate ASSIST SENSITIVITY setting.
Low Total Breath Rate	Low TOTAL BREATH RATE Alarm	1. Change in patient status; decreased patient breath rate. 2. Leak in the patient circuit. 3. Incorrect ASSIST SENSITIVITY setting. 4. Improperly set alarm. 5. Prolonged high airway pressures followed by a high PEAK INSP PRESSURE alarm have signaled the ventilator to delay the next breath until airway pressures drop to within 5 cmH₂O of baseline.	1. Re-evaluate patient status and alarm setting. 2. Check for patient circuit leaks. 3. Adjust ASSIST SENSITIVITY so patient can trigger breaths. 4. Re-evaluate alarm setting. 5. Eliminate circuit kinks. Follow the guidelines for a high baseline alarm.
High Peak Inspiratory Pressure	High PEAK INSP PRESSURE Alarm	1. Kinked or obstructed proximal airway line or expiratory leg of patient circuit. 2. Patient coughing. Endotracheal tube occlusion. 3. Change in patient's Compliance and Resistance ($\downarrow C$, $\uparrow R$). 4. Improperly set alarm; alarm limit set below observed pressure	1. Check patient circuit and remove kink/obstruction. Check for excess water in circuit; drain if present. 2. Observe patient; may require suctioning. 3. Evaluate patient status. Re-evaluate settings for TIDAL VOLUME, WAVEFORM, PEAK FLOW and PEEP. 4. Re-evaluate alarm setting. Re-evaluate PEEP plus PRESSURE SUPPORT level.

SYMPTOM	INDICATED BY	POSSIBLE CAUSES	CORRECTIVE ACTION
High Peak Inspiratory Pressure	High PEAK INSP PRESSURE Alarm	1. Patient coughing. Endotracheal tube occlusion. 2. Change in patient's Compliance and Resistance ($\downarrow C$, $\uparrow R$). 3. Improperly set alarm; alarm limit set below observed pressure.	1. Observe patient; may require suctioning. 2. Evaluate patient status. Re-evaluate settings for TIDAL VOLUME, WAVEFORM, PEAK FLOW and PEEP. 3. Re-evaluate alarm setting. Re-evaluate PEEP plus PRESSURE SUPPORT level.
Sustained High Peak Inspiratory Pressure	High Peak Insp. Pressure alarm and "PHP" in Display window.	1. Kinked or obstructed Proximal Airway line or Expiratory leg of Patient Circuit.	1. Check Patient Circuit and remove the kink/obstruction. 2. Press VISUAL RESET and verify ventilator is functioning.
Low Peak Inspiratory Pressure	Low PEAK INSP PRESSURE Alarm	1. Patient or proximal line disconnect. 2. Leak(s) in patient circuit and/or humidification system or exhalation diaphragm. 3. Change in patient's Compliance or Resistance ($\uparrow C$, $\downarrow R$). 4. Pressure support level not reached before patient terminates breath. 5. Improperly set alarm; set too high.	1. Reconnect the circuit. 2. Check for patient circuit leaks. Ensure humidifier chamber is secure. Check diaphragm for leaks. 3. Evaluate patient status. Re-evaluate TIDAL VOLUME, PEAK FLOW, WAVEFORM and PEEP settings. 4. Re-evaluate PRESSURE SLOPE setting. 5. Re-evaluate alarm setting and account for both volume-controlled and pressure-supported breaths.

SYMPTOM	INDICATED BY	POSSIBLE CAUSES	CORRECTIVE ACTION
Proximal Disconnect	PROXIMAL DISCONNECT Alarm	1. Patient or proximal line disconnect. 2. Leak(s) in patient circuit and/or humidification system or exhalation diaphragm.	1. Reconnect the circuit. 2. Check for patient circuit leaks. Ensure humidifier chamber is secure. Check diaphragm for leaks.
High Baseline Pressure	High BASELINE PRESSURE Alarm	1. Severe occlusion of expiratory leg of circuit or proximal pressure line which prevents pressure from returning to baseline during exhalation. 2. Air trapping; pressure does not fall to baseline. Possibly caused by a change in patient's Resistance ($\uparrow R$). 3. Improperly set alarm; set too low.	1. Check patient circuit for occlusion. 2. Measure any intrinsic PEEP with EXPIRATORY HOLD key. Re-evaluate PEAK FLOW setting and I:E RATIO monitor. Evaluate patient status. 3. Re-evaluate alarm setting.
Low Baseline Pressure	Low BASELINE PRESSURE Alarm	1. Patient Disconnect. 2. Leak in patient circuit. 3. Leak in exhalation valve diaphragm.	1. Reconnect the patient. 2. Check circuit for disconnects or leaks. 3. Check diaphragm for holes or tears. Perform leak test (Section 3).

SYMPTOM	INDICATED BY	POSSIBLE CAUSES	CORRECTIVE ACTION
Loss of Air Supply Pressure	GAS SUPPLY FAILURE Alarm	- Air supply inlet pressure has decreased to below 27.5 psig. - Clogged air inlet water trap/coalescing filter. - Compressor output pressure has decreased below 27.5 psig. - Inoperative air pressure sensor.	- Blender will provide 100% O₂. - Check for secure air hose connection to ventilator, compressor and wall. Restore air supply pressure. - Check air inlet gauge reading. - Check compressor power switch is on and indicator is lit. - Replace inlet filter if clogged. - Blender will provide 100% O₂. - Check the output pressure gauge on the compressor. If the reading is below 30 psig, refer unit to authorized service technician. - Remove the ventilator from the patient and provide alternate ventilation. Refer the unit to an authorized service technician.
Loss of Oxygen Supply Pressure	GAS SUPPLY FAILURE Alarm	- O₂ supply inlet pressure has decreased to below 27.5 psig with O₂% control set above 21%. - Clogged O₂ inlet coalescing filter. - Inoperative O₂ pressure sensors.	- Blender will deliver Air (21% O₂). - Check oxygen inlet gauge reading. - Check for secure O₂ hose connection to ventilator and wall. Restore O₂ supply pressure. - Replace inlet filter if clogged. - Remove the ventilator from the patient and provide alternate ventilation. Refer the unit to an authorized service technician.
Loss of Both Air and Oxygen Pressure	GAS SUPPLY FAILURE Alarm Accompanied by FAILED TO CYCLE Alarm	Air and oxygen supply pressure have decreased to below 27.5 psig.	Check for secure air and O₂ hose connections to ventilator, compressor and wall.

SYMPTOM	INDICATED BY	POSSIBLE CAUSES	CORRECTIVE ACTION
Ventilator will not Power Up	No LEDs; no audible alarms	1. AC receptacle inoperative 2. AC power cord not securely connected at one or both ends. 3. Blown fuse(s). 4. Defective power supply.	1. Try different receptacle. 2. Check both ends of power cord to ensure proper connection to the ventilator and wall outlet. 3. Replace fuse(s) (see Section 5). 4. Refer unit to authorized service technician.
Keys will not respond when pressed.	Audible tone and lack of setting change.	1. LOCK keys in the Control or Alarm panels may be active.	1. Press the LOCK keys to cause the LEDs to turn off.
When ventilator is turned on, all LEDs illuminate, but no gas flows	GAS SUPPLY FAILURE Alarm accompanied by FAILED TO CYCLE Alarm	1. Air and O₂ supply hoses disconnected or severely kinked. 2. Gas supply failure.	1. Reconnect hoses to respective sources, or unkink hoses. 2. Remove patient from ventilator and provide alternate mode of ventilation.
Visual indication of alarm condition without audible tone.	ALARM SILENCE LED lit	1. ALARM SILENCE key has been activated in the past 60 seconds.	1. Wait for 60-second time-out or press ALARM SILENCE key a second time to cancel.
Visual indicators do not light and alarms do not sound when TEST key is pressed.		1. Electrical system malfunction.	1. Refer the unit to an authorized service technician.

P.M. Kit 50000-13001
P.M. Kit compressor
50000-13051

#78

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SYMPTOM	INDICATED BY	POSSIBLE CAUSES	CORRECTIVE ACTION
Nebulizer will not deliver flow.	Nebulizer not delivering aerosolized medication.	1. NEBULIZER key turned off or 30 minutes has elapsed. 2. Flow rate, as determined by PEAK FLOW and either the WAVEFORM or PRESSURE SLOPE does not exceed 20 LPM. (10 LPM for lower tidal volume).	1. Depress NEBULIZER key and ensure associated LED is lit. 2. Flow rate must exceed 20 LPM for nebulizer to operate. (10 LPM for lower tidal volume).
	RUN DIAGNOSTICS Alarm	1. Nebulizer solenoid fault.	1. Provide alternate source of gas delivery to nebulizer. Refer unit to an authorized service technician.
Patient cannot trigger an assisted breath or obtain gas from demand system.	Low TOTAL BREATH RATE Alarm	1. Inadequate ASSIST SENSITIVITY setting or Flow Trigger setting. 2. Patient circuit leak. 3. Worn or damaged exhalation valve diaphragm.	1. Re-evaluate patient and ASSIST SENSITIVITY or Flow Trigger setting. 2. Check patient circuit for leaks. 3. Perform leak test (Section 3), and replace diaphragm if it leaks or is damaged.
Pressure level for Pressure-Supported or Pressure-Controlled breaths is low for all or a portion of the breath.	Low PEAK INSP PRESSURE Alarm	1. PRESSURE SLOPE setting too low. As a result, flow rate is below patient demand. 2. PRESSURE SUPPORT or INSPIRATORY PRESSURE setting too low.	1. Re-evaluate patient and PRESSURE SLOPE setting. 2. Re-evaluate setting.

7. CLEANING & MAINTENANCE

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OVERVIEW

The following pages provide guidelines for:

- cleaning and sterilizing the ventilator and its components,
- scheduling preventive maintenance,
- using the built-in diagnostics features, and
- performing the operational checkout.

The diagnostic features, described briefly here and more completely in the Maintenance Manual, enable an authorized service technician to troubleshoot the ventilator in detail.

Two sources of service assistance are available beyond that offered in this manual:

- The local Bear service representative or
- Bear Medical Systems, Inc. at: 1-800-232-7633 or (909)-788-2460

Before calling for service assistance, remember to review and record the Troubleshooting Code History on your BEAR® 1000 Ventilator. This history is a valuable tool to the service representative who will be assisting you. The steps for reviewing the Troubleshooting Code History are described in this section.

The same headquarters phone number can be used to learn about the Bear service contract options as well as biomedical training offerings.

CLEANING & STERILIZATION

The following table provides a comprehensive guide to suggested cleaning and sterilization of your BEAR® 1000 Ventilator.

CAUTION

Do not sterilize the BEAR® 1000 Ventilator. Internal materials are not compatible with sterilization techniques. To avoid possible damage to elastomeric components, maximum temperatures for sterilization are: Ethylene Oxide—125 °F (52 °C) and Autoclave—250 °F (121 °C).

When liquid sterilizing agents are recommended, those which have been thoroughly tested include glutaraldehyde-based agents such as: "Cidex," "Sonacide" and "Sporicide." Many liquid disinfectant agents are purchased in a concentrate. Follow the manufacturer's recommendation for solution preparation. High concentrations and repeated applications of liquid disinfectant will degrade some plastic, yielding damaged or leaking parts. Therefore, all parts should be tested periodically for leaks.

COMPONENT	FREQUENCY	METHOD
Ventilator Panels	As Needed	Wipe with water or 70% Isopropyl Alcohol, only.
Ventilator Enclosure	As Needed	Wipe with any bactericidal agent, but do not allow liquid to penetrate the inside of the ventilator
Panel Overlay for Service Diagnostics	As Needed	Wipe with 70% Isopropyl Alcohol
Exhalation Valve Assembly:		
Diaphragm Mounting	Between Patients	Wipe with 70% Isopropyl Alcohol
	Every 30 days	Sterilize ^a
Diaphragm	Between Patients	Sterilize ^a
Manifold	Between Patients	Sterilize ^a
Condensate Jar	Between patients	Sterilize ^a
Air/Oxygen Water Trap Bowls	As needed	Sterilize with liquid or gas ^c
Cart Enclosure	As needed	Wipe with 70% Isopropyl Alcohol
Patient Circuit:		
Mainflow Bacteria Filter	Between patients ^d	Sterilize ^a
Proximal Line Hydrophobic Filter	Between patients ^d	Sterilize ^a
Universal Filter Connectors	Between patients ^d	Sterilize ^a
Reusable Circuit Tubing	Between patients ^d	Sterilize ^a
Patient Wye	Between patients ^d	Sterilize ^a
Tygon® Tubing	Between patients ^d	Sterilize ^a
Infant Tube Connectors	Between patients ^d	Sterilize ^{a, b}
Adapters	Between patients ^d	Sterilize ^{a, b}
Endotracheal Connectors	Between patients ^d	Sterilize ^{a, b}
Tapered Flex Tubes	Between patients ^d	Sterilize ^{a, b}

^aAny of the following processes: Gas, Liquid, Autoclave, or Pasteurize.

^bThese parts are on Pediatric Circuits only.

^cCold cycle only. Do not exceed 125°F or 52°C.

^dBetween patients or according to usual hospital protocol.

VarFlex® Flow Sensor Sterilization Instructions

CAUTION

Do not attempt to dry internal components of the flow sensor body with a high pressure air hose as this will damage the sensor.

CAUTION

Do not insert cleaning instruments (brushes, pipe cleaners, etc.) into the flow sensor. Doing so can damage the sensor.

The flow sensor is an integral part of the Flow Trigger system. If a Run Diagnostic alarm is active with an E-34 or E-35 error code (Flow Sensor Fault), Flow Triggering should be discontinued. If an E-34 or E-35 condition is active, possible de-sensitivity to patient effort will occur.

The BEAR® 1000 Ventilator VarFlex® Flow Sensor may be sterilized utilizing either ethylene oxide (EtO), liquid, steam autoclave or pasteurization techniques. To avoid damage to elastomeric components, maximum sterilization temperatures should not exceed 130°F (54°C) for ethylene oxide and 275°F (135°C) for steam autoclave (100 autoclave cycles maximum).

Following liquid sterilization, thoroughly rinse the flow sensor and pressure sensing lines with distilled water to remove any residual sterilization agent. It may be necessary prior to drying the flow sensor to purge the pressure sensing lines with clean Air or Oxygen, if liquid is observed to remain in the tubing following the rinse process. To do so, simply introduce a flow of less than 10 LPM of gas (Air or Oxygen at less than 2 psig) into one of the open pressure sensing line ports on the connector end of the flow sensor to purge the line of any residual liquid. Repeat the process for the remaining pressure sensing line port, then reexamine the tubing for traces of liquid. If the pressure sensing line tubing is free of liquid, complete the drying process in an aeration cabinet.

If any liquid remains in the pressure sensing line tubing following utilization of an approved sterilization method, please refer to the above for instructions on purging the lines.

Beyond the cleaning and sterilization guidelines described, a well-structured maintenance program is essential for continuous uninterrupted functioning of the ventilator. Accordingly, preventive maintenance guidelines follow. When needed, refer to Section 9 for information on replacement parts.

PREVENTIVE MAINTENANCE SCHEDULE

Preventive Maintenance Schedule

FREQUENCY	ACTION
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Between Patients CHANGE EXHALATION VALVE & FLOW SENSOR: Change the Exhalation Valve and Flow Sensor as follows:

- Remove the Flow Sensor, Exhalation Valve Manifold, Condensate Jar, and Diaphragm.
- EITHER
 - 1) Wipe the outside of the Diaphragm Mounting Base Assembly with a bacteriocidal agent, OR 70% isopropyl alcohol.
 - 2)
 - a. Remove the Diaphragm Mounting Base Assembly from the exhalation valve port.
 - b. Install a clean Diaphragm onto the Diaphragm Mounting Base Assembly and perform a leak test on the Diaphragm. Replace the Diaphragm if it leaks.
 - c. Re-install the Diaphragm Mounting Base Assembly into the exhalation valve port.
- Reinstall a clean Manifold, Condensate Jar and Flow Sensor.

INSPECT FOR LEAKS OR CRACKS in all portions of the patient breathing circuit, including: tubing, adapters, Exhalation Valve and Flow Sensor. Replace all worn parts.

INSPECT AIR & O₂ INLET WATER TRAPS: Check for any water or visible contaminant build-up. Evidence of either of these is cause for replacing the filters and cleaning the bowls. The presence of water indicates the possibility that water may be entering the ventilator. Contaminants which cause clogging or occlusion of the intake filter can cause equipment malfunction.

CAUTION

Condensate in the water traps warns that condensate may be entering the ventilator. If the compressed air and oxygen entering the ventilator is not clean and dry, ventilator malfunction may result. Therefore, check the water traps periodically.

TEST AUDIBLE & VISUAL ALARMS: Verify the proper operation of all Audible and Visual Alarms by pressing the red TEST key and observing all the LEDs light and the alarm sound. The ventilator continues to ventilate normally during this test.

PERFORM OPERATIONAL CHECKOUT: Perform the Quick Operational Checkout described in Section 3.

FREQUENCY	ACTION
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Once a Month PERFORM PART ONE OF THE OPERATION VERIFICATION PROCEDURE (OVP)

INSPECT O-RING: Inspect the o-ring on the exhalation valve Diaphragm Mounting. Replace this o-ring if there is evidence of cracking or warping.

VACUUM ENCLOSURE AIR INTAKE FILTER: The ventilator enclosure intake filter removes contaminants from the air drawn into the case by the fan. Vacuum clean this filter once every 500 hours of operation.

CAUTION

A clogged or occluded air intake filter on the ventilator enclosure can cause equipment malfunction.

TEST BACTERIA FILTERS: Test both Mainflow and Proximal Line filters for increased resistance. The filter resistance tests are described on following pages. The filters should be replaced whenever they fail the resistance test or they reach their one year retirement date, whichever occurs first.

Every 6 Months **DISCARD AND REPLACE O-RING AND DIAPHRAGM:** Replace the o-ring on the exhalation valve Diaphragm Mounting Base Assembly and Exhalation Diaphragm. Replace any worn damaged or leaking parts.

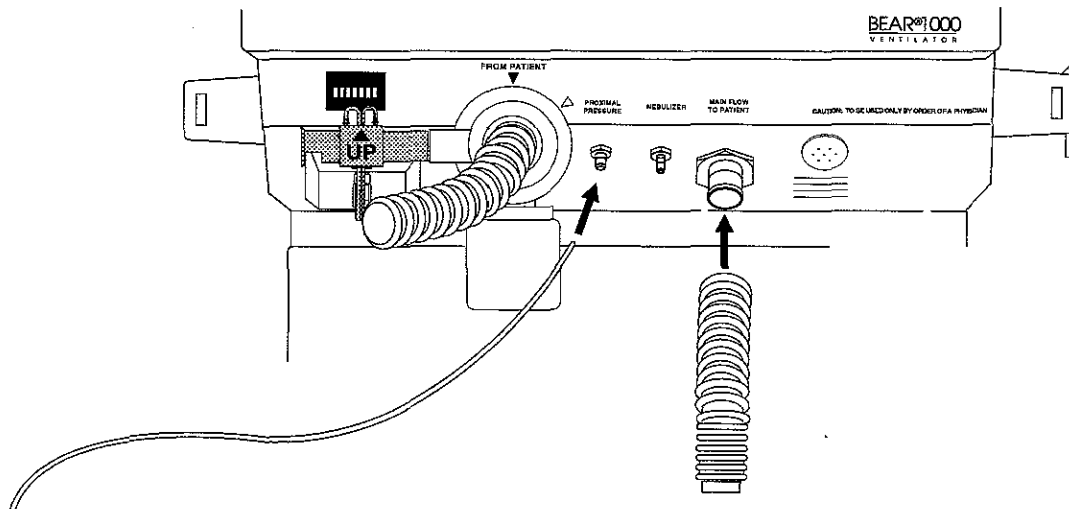
PERFORM PART TWO OF THE OPERATION VERIFICATION PROCEDURES.

Every 12 Months **REPLACE REUSABLE BACTERIA FILTERS:** (both Mainflow and Proximal Line).

INSTALL PREVENTIVE MAINTENANCE KIT (P/N 50000-13001) and verify calibration. **NOTE:** Preventive Maintenance consists mainly of filter replacements and performance verification. Refer to the BEAR® 1000 Ventilator Maintenance Manual, Section 9, for detailed procedure.

FILTER RESISTANCE TEST

The maintenance schedule calls for a bacteria filter resistance test to be performed at least monthly. This test is described below for both the Mainflow Bacteria Filter and the Proximal Line Hydrophobic Filter. The procedure differs slightly for each of the two filters, and these differences are highlighted below.



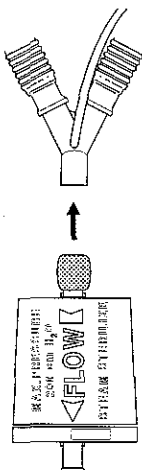
- 1) Remove one of the filters from the circuit and,

Mainflow Filter

Reconnect the inspiratory leg of the circuit directly to the ventilator port labeled "Main Flow to Patient."

Prox Line Filter

Reconnect the 4- to 6-foot length of $\frac{1}{4}$ " tubing directly to the proximal pressure fitting.



- 2) Connect one of the filters to the patient side of the Patient Wye making sure to observe the direction of flow on the filter.

Mainflow Filter

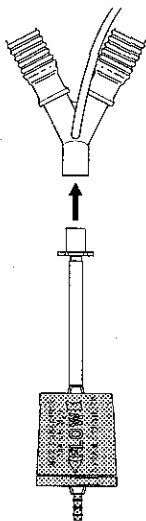
Use the blue filter Coupler to connect the filter to the wye.

Prox Line Filter

Use a short length of $\frac{1}{4}$ " tubing and a 15mm OD/ 7mm OD endotracheal adapter to connect the filter to the wye.

- 3) Set the control parameters as follows, depending upon which filter is being tested.

PEAK INSP PRESSURE	<u>Mainflow Filter</u>	<u>Prox Line Filter</u>
Alarm	120 cmH ₂ O	same
MODE	Assist CMV	same
TIDAL VOLUME	2.00 L	same
RATE	10 BPM	same
PEAK FLOW	120 LPM	10 LPM
O ₂ %	21	same
PRES SUP/INSP PRES	0 cmH ₂ O	same
INSPIRATORY PAUSE	0.0 seconds	same
PRESSURE SLOPE	0	same
WAVEFORM	Square	same
SIGHS	Off	same
NEBULIZER	Off	same



- 4) With gas flowing through the filter, record the peak proximal pressure reading during a mechanical breath.
- 5) Remove the filter (but not its connector) from the patient wye, and again record the peak proximal pressure reading during another mechanical breath.
- 6) The difference between the pressure readings in step 4 and 5 represents the resistance to flow produced by the bacteria filter. If the resistance for either filter type is more than 4.0 cmH₂O, that filter has failed the resistance test and should be discarded.

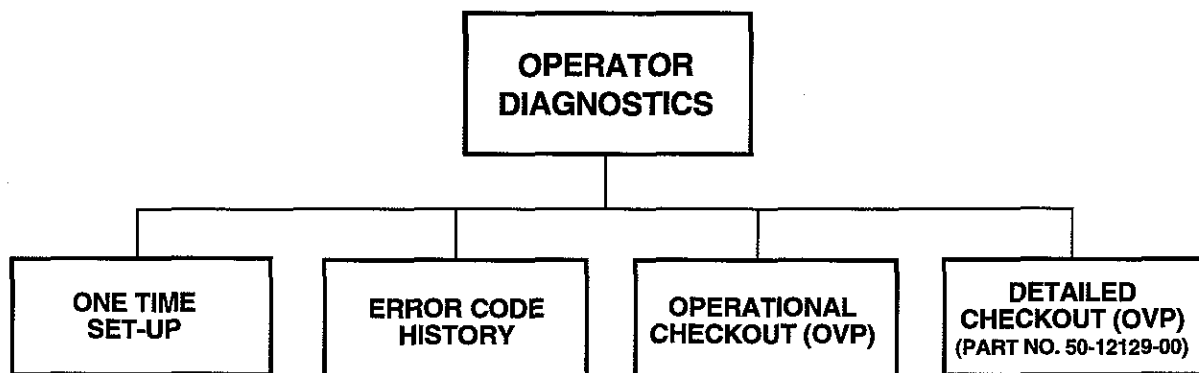
DIAGNOSTICS OVERVIEW

The automated diagnostic capabilities of the BEAR® 1000 Ventilator are divided into two groups: the Operator Diagnostics and the Service Diagnostics. Operator Diagnostics are used primarily by the clinician while the Service Diagnostics are used only by authorized service technicians.

As the Diagnostics Diagram shows, Operator Diagnostics is composed of four elements.

- First is the one-time setup described in detail in Section 2. This setup is likely to occur only when the ventilator is first received from the factory. It establishes the appropriate altitude setting and communication baud rate.

- Second is the Troubleshooting Code History. This feature is described on following pages. It enables the user to review the past 16 troubleshooting codes experienced by the ventilator.
- Third is the Quick Operational Checkout, partially described in Section 3. A more complete description is provided in this section.
- Fourth is the Detailed Checkout procedure which takes the Operational Checkout to a greater level of detail. This detailed checkout is also called the "Operational Verification Procedure" or OVP. It should be performed when the ventilator is first received from the factory and bi-yearly. The procedure is described in a separate document (P/N 50-12129-00) as well as in the Maintenance Manual.



The Service Diagnostics is composed of two elements.

- Calibration, and
- Service Troubleshooting.

TROUBLESHOOTING CODE HISTORY

The Troubleshooting Code History can be accessed through the Operator Diagnostics. This history is valuable for troubleshooting the ventilator, and should be reviewed and recorded whenever possible prior to contacting a Bear service technician. Because the entire history is accessed through the Operator Diagnostics mode, it cannot be reviewed when the unit is in any other mode of operation, such as while ventilating a patient. Only the single most recent troubleshooting code can be viewed during ventilation, by pressing the TEST key (before pressing the VISUAL RESET key.)

To review the entire Troubleshooting Code History, first enter the Operator Diagnostic mode by following these steps:

- 1) Locate the TEST key on the front panel at the right of the red Alarm Group.
- 2) Press and hold this key while reaching to the rear of the ventilator and turning on the power switch. Hold the TEST key until the Diagnostic displays appear.
- 3) Verify that the Operator Diagnostics mode is activated by observing the RUN DIAGNOSTICS LED light.

Other LEDs will light, and although they convey valuable information for detailed troubleshooting, they are not needed for reviewing the Troubleshooting Code History. A brief summary of these key functions is provided in the diagram below. For more information on these readouts, refer to the Detailed Checkout/OVP, the Maintenance Manual or the Panel Overlay for Service Diagnostics.

Review the troubleshooting codes by:

- 1) Pressing the PEAK FLOW control key and turning the green Control SET knob.
- 2) Observe and record the:

Count Number in the PEAK FLOW display (1-16) with 1 being the oldest code on record;

Code Number in the O₂% display (E1 – E51). See Section 6 for a definition of each of these codes.

NOTE

When code number EO is displayed, it means **no** code is present.

KEY FUNCTION DURING:

NORMAL VENTILATION

OPERATOR DIAGNOSTICS

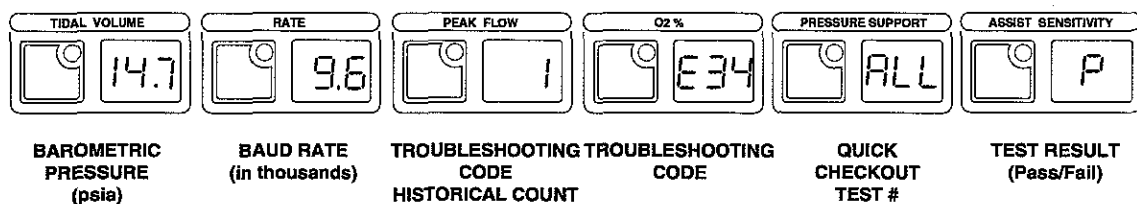


Figure 7-1 • Some of the Key Functions During Operator Diagnostics

QUICK OPERATIONAL CHECKOUT

The Quick Operational Checkout capability of your BEAR® 1000 Ventilator is accessed through the Operator Diagnostics mode. Section 3 of this manual (*Setup & Checkout*) provides a step-by-step description of how to perform this automated procedure. In the course of a complete automated test, all of the major subsystems of the ventilator are checked with the exception of the:

- Air inlet pressure sensor
- Oxygen inlet pressure sensor
- Fan
- Nebulizer solenoid
- PEEP Valve

These subsystems are instead checked as a part of the Detailed Checkout/OVP described in a separate document.

Follow the seven steps outlined in Section 3 of this manual to perform the complete set of seven automated tests which are part of the Quick Operational Checkout. Recognize that if any of these tests fail, the ventilator will stop at that test; it will not perform subsequent tests because accuracy of subsequent tests can depend upon the success of previous ones.

If you wish to run a particular test rather than all seven, perform the steps described in Section 3, but at Step #3, press the PRESSURE SUPPORT key and turn the green control SET knob until the desired test number appears in the adjacent LED. Table 7A defines each test. Remember that test d04 "Leak Test," should be run before d05 through d07 since a leak in the system may cause these later tests to fail.

Once the desired test has been selected:

- Press the MANUAL BREATH key to run the test once.
- Press the MANUAL PAUSE key to run the test repeatedly until it is cancelled or a failure occurs.
- Press the EXPIRATORY HOLD key to cancel the current test.

WARNING

If the unit fails repeatedly to pass the Quick Operational Checkout, it should be referred to an authorized service technician.

Table 7-A**Quick Operational Checkout Tests**

Test	Corrective Actions
d 1 Microprocessor and memory self check	Refer unit to an authorized service technician.
d 2 Flow Control Valve mechanics and electronics	Refer unit to an authorized service technician.
d 3 Blender control valve mechanics and electronics	Refer unit to an authorized service technician.
d 4 Leaks in ventilator, circuit or exhalation valve	Check for leaks. If not corrected by leak test, then refer unit to an authorized service technician.
d 5 Flow delivery and external flow sensor accuracy	Try a new Flow Sensor. If not corrected, then refer unit to an authorized service technician.
d 6 SOPR valve test	Refer unit to an authorized service technician.
d 7 Pressure delivery and sensing test	Make sure patient circuit is 72" and PEEP knob is turned full counterclockwise. If not corrected, then refer unit to an authorized service technician.

8. THEORY OF OPERATION

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OVERVIEW

This section provides an in-depth discussion of the operating theory of the BEAR® 1000 Ventilator. Included are descriptions of the:

- ventilator pneumatics,
- electronics (including Monitor PCB, Control PCB and EPI),
- flow delivery logic, and
- RS-232 protocol.

Figure 8-1 shows how these parts of the ventilator interrelate.

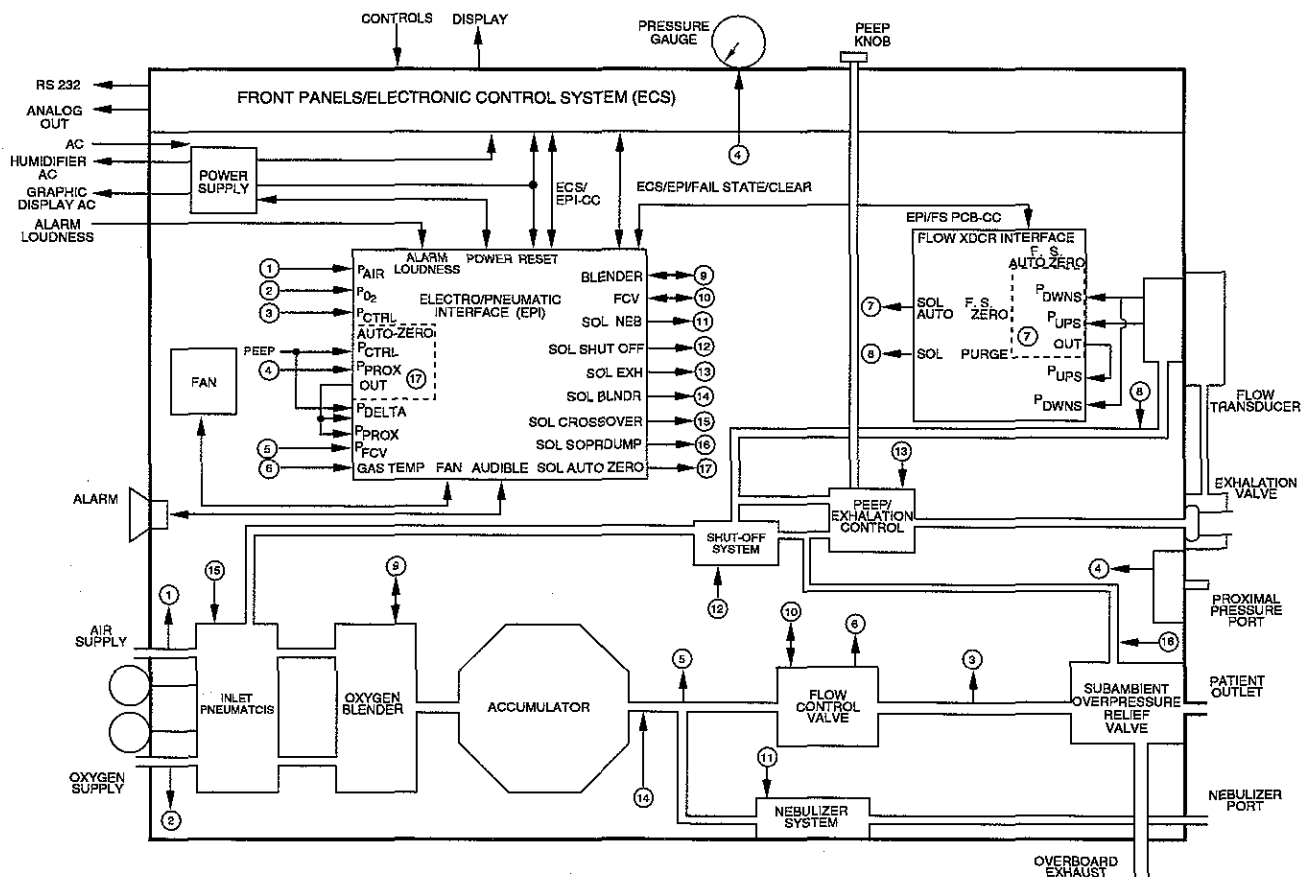


Figure 8-1

VENTILATOR PNEUMATICS

Figure 8-2 depicts the complete pneumatics of the BEAR® 1000 Ventilator.

GAS INLET SYSTEM

Compressed air and oxygen sources, supplied in the pressure range of 30 to 80 psig, are connected to the standard DISS male-threaded fittings on the rear of the ventilator.

Incoming gases pass through coalescing filters housed in the Air and O₂ Inlet Water Traps. The filters have a minimum retention efficiency of 95% for 0.7 micron particles and 2 micron droplets.

The inlet pressures of the gases are monitored by independent air and oxygen Inlet Pressure Transducers, and are displayed on their respective inlet pressure gauges. A drop in either gas pressure below 27.5 psig activates an audible and visual GAS SUPPLY FAILURE alarm.

From the Inlet Water Traps and Filters, the air and oxygen enter the in-line, one-way Check Valves which prevent gas backflow into the air and oxygen supply systems. To prevent check valve malfunction, compressed gases must be clean and dry.

The Air Regulator and Oxygen Relay create a balance of air and oxygen supply pressures. The Air Regulator reduces the air supply pressure to 18.0 psig and pilots the O₂ Relay to track at the same pressure. This balance ensures the accuracy of downstream air and oxygen blending.

In the event air is lost, the Crossover Solenoid opens, delivering high pressure oxygen to the Air Regulator, which in turn regulates the O₂ Relay.

BLENDER

Air and oxygen enter the Blender and mix to the desired oxygen concentration selected by the O₂% control on the ventilator front panel. The Bleed Solenoid bleeds a small constant flow from the blender, to ensure accurate blending at low flow rates.

In the event of a GAS SUPPLY FAILURE alarm, caused by a drop in air or oxygen supply pressure (to below 27.5 psig), the Blender switches over completely to the remaining gas supply. Either 100% oxygen or 100% air (i.e., 21% oxygen) is supplied to the patient.

WARNING

When a GAS SUPPLY FAILURE alarm occurs, the Blender will use the remaining gas supply. This means that the oxygen concentration delivered to the patient may differ from the clinician-selected O₂ setting.

If an error is detected in the Blender during power-up, a RUN DIAGNOSTICS alarm activates both audibly and visually.

ACCUMULATOR

Blended gas leaves the Blender and enters the rigid 3.5 liter Accumulator. Under both low and no output-flow conditions, the mixed gas from the Blender fills the accumulator until it reaches system pressure (18.0 psig). In response to an output flow demand, the stored volume in this Accumulator is supplied to the Flow Control Valve, thereby reducing the instantaneous flow demand imposed on the Blender. This minimizes flow-generated pressure transients upstream, and thus maintains stable O₂ concentrations at the Blender output.

The Accumulator has two important functions:

- It acts as a mixing chamber for the blended gas, resulting in increased stability of the oxygen concentration.
- It allows for high peak output flows of over 200 LPM while only requiring a relatively low (80 LPM) gas input from the wall.

FLOW CONTROL VALVE

Blended gas from the Accumulator enters the Flow Control Valve (FCV) at 10–18 psig of pressure. This inlet pressure varies due to the gas storage function of the Accumulator.

Both ventilator control settings and patient demand together determine the output flow from the FCV.

Whatever the output flow established by the flow delivery logic, the temperature sensor built into the FCV enables the ventilator to deliver accurate volumes based upon a standard temperature correction, 77°F, zero saturation humidity and the set barometric pressure.

The FCV delivers peak flows in the range of:

Volume-controlled Breaths: 10 to 150 LPM

Demand or Pressure Breaths: 0 to over 200 LPM

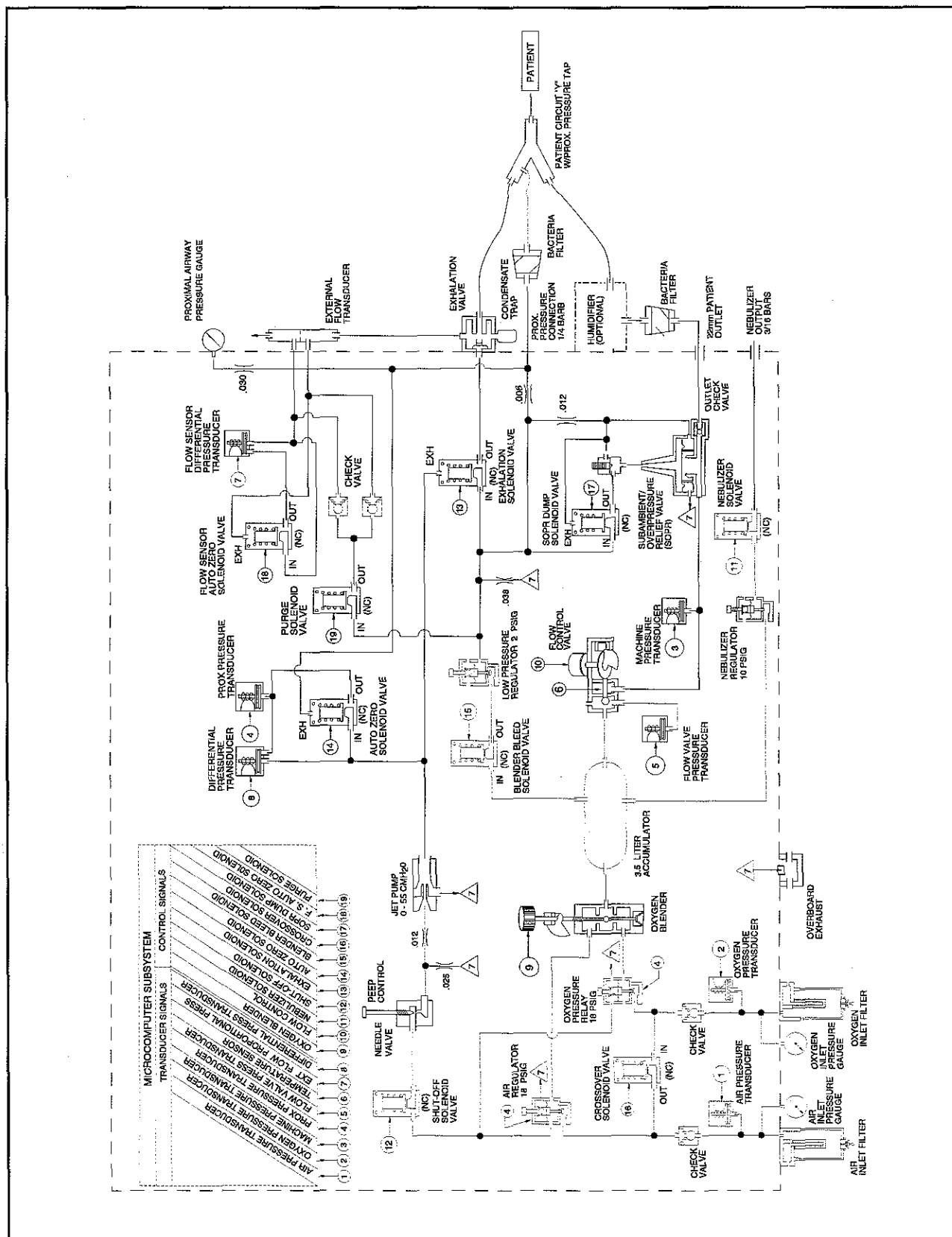


Figure 8-2 • Pneumatic System Diagram

SOPR VALVE

From the FCV, the gas flows through the Subambient Overpressure Relief Valve (SOPR) and out of the ventilator through the port labeled "Main Flow to Patient."

During normal operation, the Low Pressure Regulator supplies 140 cmH₂O to the SOPR valve diaphragm, thereby closing its relief port. Because this port is closed, gas from the FCV passes directly through the SOPR and out to the patient.

When the Fail State System activates (due to a FAILED TO CYCLE alarm or a power failure), the 140 cmH₂O normally supplied to the SOPR valve diaphragm falls to zero, and the SOPR relief port opens. When the relief port opens, the patient can breathe room air.

Beside providing the patient with access to room air, the SOPR has a second function. It acts as an independent relief valve to mechanically limit the maximum pressure the ventilator can deliver. This mechanical limit functions only when ventilator outlet pressure exceeds 175 cmH₂O. Such a high pressure on the front side of the SOPR relief port causes the port to open and thereby relieve excess gas through the outlet labeled "Over-board Exhaust."

LOW PRESSURE CONTROL SYSTEM

The Low Pressure Control (LPC) System serves three functions:

- It provides 140 cmH₂O to the SOPR valve diaphragm, and
- It controls the Exhalation Valve Diaphragm to determine breath phase (inspiration vs. exhalation) and PEEP level,
- It supplies gas for the Proximal Line and Flow Sensor Purge.

The LPC System consists of the following components:

- Shut-off Solenoid Valve
- Low Pressure Regulator
- PEEP Needle Valve
- PEEP Jet Pump
- Exhalation Solenoid Valve
- Flow Sensor Purge Solenoid

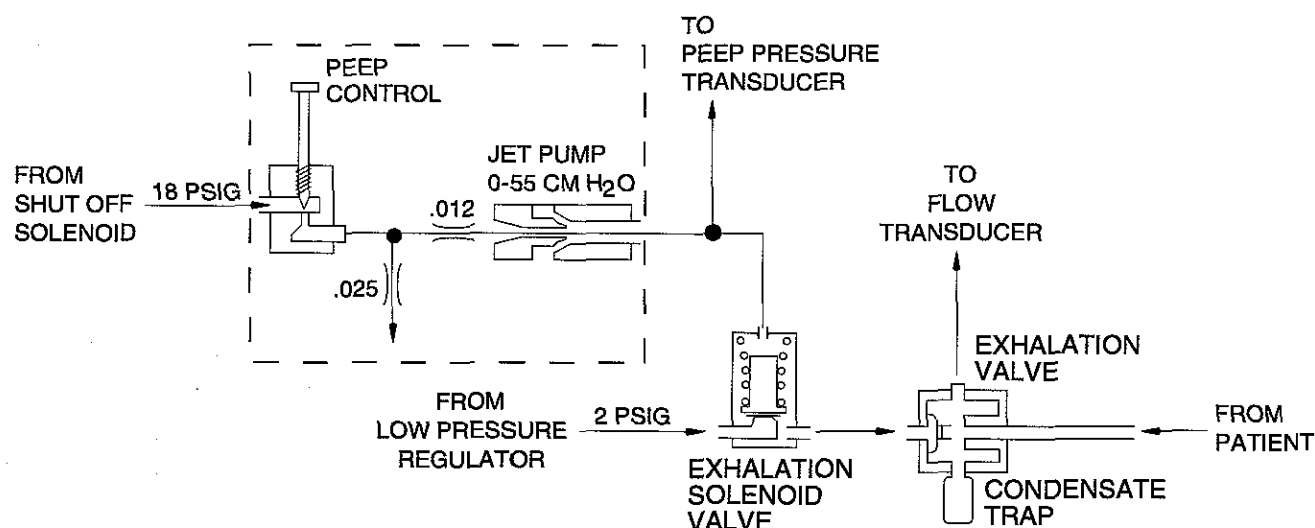


Figure 8-3 • Low Pressure Control System

After entering the ventilator and passing through the regulator, air is tapped off before entering the Blender. This sidestream of 18 psig gas feeds directly into the Shut-off Solenoid Valve.

During normal operation, the Shut-off Solenoid Valve is energized, passing 18 psig gas from the Gas Inlet System to both the Low Pressure Regulator and the PEEP Needle Valve. Under this circumstance, the LPC System functions as follows:

1. SOPR Valve: The 140 cmH₂O from the Low Pressure Regulator enters the SOPR valve diaphragm, thereby holding its relief port closed.
2. Exhalation Valve and PEEP Control: The Exhalation Solenoid Valve switches the reference pressure for the Exhalation Valve Diaphragm between:
 - The 140 cmH₂O supplied by the Low Pressure Regulator, and
 - The output pressure from the combination of the PEEP Needle Valve and the PEEP Jet Pump.

This allows the Exhalation Valve to close during inspiration and maintain PEEP during exhalation.

By contrast, during Fail State Operation (a FAILED TO CYCLE alarm or a power failure), the LPC System functions as follows:

1. SOPR Valve: The Shut-off Solenoid Valve de-energizes and closes. This cuts off the pneumatic drive to the Low Pressure Regulator which in turn, cuts off gas pressure to the back side of the SOPR Valve, thereby causing its relief port to open, and allowing the patient to inhale room air.
2. Exhalation Valve and PEEP Control: The closing of the Shut-off Solenoid Valve deprives the PEEP Needle Valve of drive pressure. The PEEP Jet Pump consequently exhausts all pressure applied to the Exhalation Valve. Because the Exhalation Valve is also de-energized by the Fail State System, it references this zero PEEP pressure being supplied by the PEEP Needle Valve and Jet Pump. As a consequence the Exhalation Diaphragm opens completely, allowing the patient to exhale, unimpeded.

EXHALATION VALVE

The Exhalation Valve regulates all flow out of the patient circuit. Exhaled patient gases flow through the expiratory leg of the patient circuit, past the Exhalation Valve Diaphragm and Seat, and through the External Flow Sensor. The Exhalation Valve is designed to minimize pressure fluctuations as well as audible noise.

The pressure to:

- Close the Exhalation Valve during a positive pressure inspiration and
- Control the baseline (PEEP) pressure

comes from the Exhalation Solenoid.

The Exhalation Valve also acts as a check valve so the patient cannot rebreathe gas through the expiratory leg of the circuit.

A condensate jar attached to the Exhalation Valve Manifold collects condensed water from the circuit and manifold.

EXTERNAL FLOW SENSOR

The External Flow Sensor, connected to the Exhalation Valve Manifold, measures exhaled tidal volumes. The flow sensor is a variable orifice, differential pressure pneumotach. The flow sensor assembly consists of a sensor head, cable (two lumen pneumatic line) and a connector. The sensor head is a two chamber component separated by a stainless steel diaphragm which provides a differential pressure output which is proportional to the flow traveling through the sensor. The differential information is then passed along through the cable and connector

to the Flow PCB for processing. The connector assembly contains two male pneumatic ports, four electronic pins and an EEPROM (Electrically Erasable Programmable Read Only Memory) integrated circuit which stores the flow characterization table specific to that sensor. EEPROM data is uploaded to the ventilator via flow PCB during the ventilator power-up or when a sensor is connected to the ventilator. The connector incorporates a sleeve which provides a positive locking mechanism to prevent unintended disconnects. During operation, a self calibrating feature insures that measurement accuracy is maintained. The pressure sense lines are purged periodically to prevent contamination from entering the ventilator and to keep the lines clean of condensation.

The Flow Sensor volume reading can be reduced by 5% if the need arises. This may be required for different types of humidification systems (heated vs. artificial nose). By default, the ventilator is set to 5 which provides no compensation. To decrease the volume by 2%, set the window to 3. To do so, perform the following steps:

1. In user or service diagnostics, press and hold the Inspiratory Pressure key, located in the green Control Group on the front panel.
2. Notice that while holding the key, the LED flashes.
3. While the LED flashes, turn the green SET knob located on the right side of the Control Group.
4. Observe the value displayed in the window, then adjust to the appropriate setting.

NEBULIZER SYSTEM

When the NEBULIZER key on the ventilator control panel is activated, the Nebulizer Regulator and Nebulizer Solenoid Valve together allow nebulization during the inspiration phase, synchronized with patient breathing.

The Nebulizer Regulator reduces the 18 psig pressure from the Accumulator to 10 psig.

While the solenoid valve is open, 6 LPM is assumed to flow through the nebulizer (the actual amount depends upon the specific nebulizer being used.) This 6 LPM is subtracted from the flow delivered by the FCV. In this manner the overall flow (nebulizer plus Main Flow output port) and volume are maintained at the clinician-set or patient demanded levels.

VENTILATOR ELECTRONICS

ELECTRONICS Monitor PCB & Control PCB

The oxygen concentration of the nebulizing gas is the same as that on the O₂% control.

The five major components of the electronics are the Monitor PCB, the Control PCB, the Electro-Pneumatic Interface (EPI) PCB, the Flow Sensor PCB, and the Power Supply.

The user operates the ventilator through the front panel controls and displays.

The Monitor and Control PCBs constantly scan the front panel for current settings or for clinician-generated changes. If a membrane key is selected, the Monitor and Control PCBs couple this parameter to the control knob. An optical encoder senses knob rotation and increases or decreases the currently displayed value accordingly.

The Monitor and Control PCBs receive patient and machine status information from the Electro-Pneumatic Interface (EPI) PCB. Based on clinician-selected control settings and EPI feedback, algorithms within the Control PCB calculate the required delivered gas flow, O₂ concentration, and Exhalation Valve state. The Control PCB transmits this information to the EPI PCB, which executes changes to the appropriate electro-mechanical devices.

Another major function of the Monitor and Control PCBs is to monitor and display the ventilator's clinical data. When monitored parameters deviate beyond clinician-set alarm limits, the Monitor and Control PCBs create audible and visual alarms.

The Control PCB also has a RS-232 9-pin digital communication port to communicate continuous real time, control, monitor and alarm data to external devices. The RS-232 communication port transmits data either to the optional BEAR® Graphics Display, or a computer. For a detailed description of the protocol, refer to the end of this section. There is also a 15-pin analog port for use in obtaining real time outputs of pressure, flow and volume signals as defined in the *Panel Details & Specifications* section.

ELECTRONICS EPI & Flow Sensor PCB

The major purpose of the EPI is to provide an interface between the Control PCB and the pneumatic hardware. The EPI receives the desired flow, oxygen concentration, and solenoid valve states every 10 milliseconds from the Control PCB. Based on this information, the EPI commands the individual electro-mechanical components to move to their correct positions.

ELECTRONICS Fault Detection

The second function of the EPI is to read the various transducer outputs, digitize the data and transmit it to the Control PCB for processing. Six pressure transducers, mounted on the EPI monitor: Proximal Airway Pressure, Machine Pressure, Proximal/PEEP Differential Pressure, Flow Control Valve Pressure, and Air and Oxygen Supply Pressures. In addition to the various transducers, the Autozero Solenoid is also mounted on the EPI. During power up *only*, the Autozero Solenoid valve is briefly energized (opened). During this time, the solenoid is used to zero the Proximal/PEEP Differential Pressure Transducer.

The EPI PCB also interfaces with the FLOW SENSOR PCB. On the FLOW SENSOR PCB is a differential pressure transducer, analog to digital converter, two solenoids and support electronics required for data communication. Analog to digital converted pressure differential information and transducer purge and auto zero solenoid functions are all controlled by the EPI PCB.

The BEAR® 1000 Ventilator, through its own operating hardware and software, continuously monitors itself for subsystem failures. Depending upon the type of failure detected, one of two states will occur:

- Alarm State: an alarm activates to alert the operator of the failure, nevertheless ventilation continues; or
- Fail State: the system activates the "Fail State" system; the ventilator ceases to operate, but the patient is allowed to breathe room air and exhale unimpeded.

If the Fail State activates:

1. All solenoids de-energize. The Shutoff Solenoid removes pneumatic drive pressure to the SOPR Valve diaphragm, PEEP Needle Valve and Exhalation Diaphragm Solenoid Valve, thereby opening the SOPR and Exhalation Valves to atmospheric pressure. The Exhalation Diaphragm Solenoid sets the Exhalation Valve reference pressure to zero. The Nebulizer Solenoid shuts off all nebulizer flow.
2. The EPI closes the Flow Control Valve electronically to prevent additional gas from being delivered to the patient.
3. The patient has access to room air through the SOPR valve.

The BEAR® 1000 Ventilator has three independent mechanisms for detecting these failures in the system:

1. Control PCB Detected Failures
2. EPI PCB Detected Failures
3. Loss of DC Power

ELECTRONICS

Power Supply

The Power Supply converts AC line voltage to DC voltages for the electrical system. If there is a temporary AC line power failure, the Power Supply provides DC power until the voltage in the capacitors drops to below 20.4 VDC. This residual voltage provides more than 300 milliseconds of continuing operation, allowing for alarm-free operation during the most common types of electrical power failure.

Once the voltage in the capacitors reaches 20.4 VDC, the Power Supply causes the ventilator to enter the Fail State, and the following occurs:

1. The alarm sounds for a minimum of 5 minutes.
2. The Flow Control Valve closes and the SOPR valve opens to allow the patient to breathe room air.

NOTE: PEEP is not maintained.

3. The ventilator power shuts off.

Once the Flow Control Valve is closed, +5 VDC is left for the ECS and EPI microprocessors, which continue to run until the +5 VDC is lost. This provides enough power for the microprocessors to store any troubleshooting codes to the EEPROM for later review.

FLOW DELIVERY LOGIC

The logic controlling the flow delivered by the FCV physically resides on the Control PCB. The logic is composed of two parts: Volume Logic and Pressure Logic.

The Volume Logic determines how much flow should be provided by the FCV to achieve volume-controlled breaths. At the same time, the Pressure Logic determines how much flow should be provided by the FCV to achieve:

- All pressure breaths, including pressure-supported, pressure-controlled, and pressure-augmented;
- All demand breaths, including spontaneous breaths, flow and volume augmentation and leak makeup.

As suggested, the capability called the "Demand System" resides within the Pressure Logic of the BEAR® 1000 Ventilator.

Figure 8-4 shows how two messages (one from the Volume Logic and the other from the Pressure Logic) are compared by the "Comparison" Logic. The "Comparison" Logic then sends the larger of the two messages to the FCV which implements flow delivery.

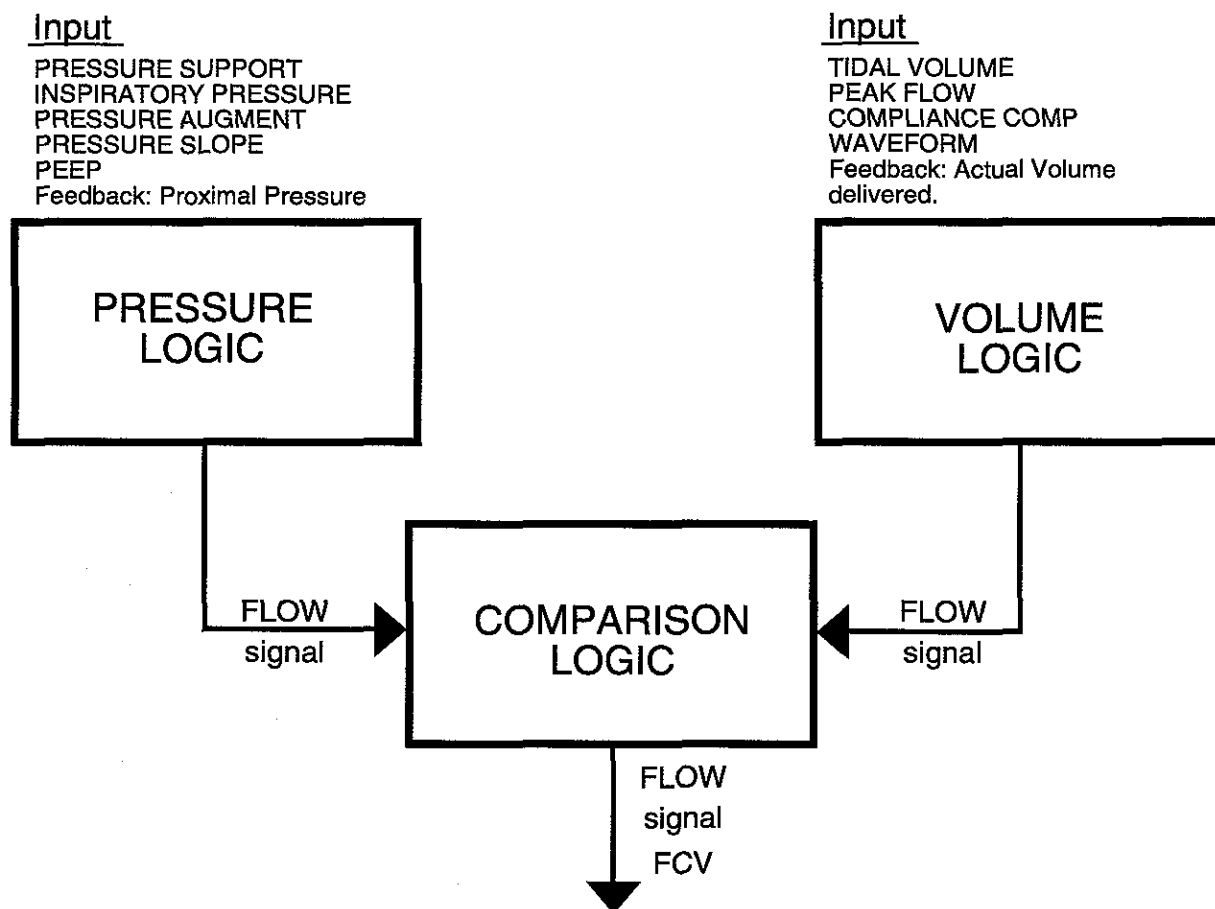


Figure 8-4 • Flow Delivery Logic

VOLUME LOGIC

When a patient passively receives a volume-controlled breath, the Volume Logic uses the preset TIDAL VOLUME, PEAK FLOW, and WAVEFORM to calculate a flow signal that is sent to the "Comparison" Logic.

Because this is a passively-received breath, the Pressure Logic sends a zero flow signal to the "Comparison" Logic. The "Comparison" Logic then compares these two signals and sends the larger one (which in this case is the Volume flow signal) to the FCV.

The Volume Logic uses feedback information from the FCV regarding actual delivered volume to determine when to switch to sending a "zero flow" signal to the "Comparison" Logic. This occurs when the TIDAL VOLUME and the optional COMPLIANCE COMP volume have been delivered.

PRESSURE LOGIC

Demand breaths rely solely upon the Pressure Logic to determine the flow output from the FCV.

When a patient initiates a demand breath, proximal airway pressure drops below baseline. The Pressure Logic (in the Control PCB) sends a signal through the "Comparison" Logic to the FCV instructing it to respond with sufficient flow to maintain proximal airway pressure at either:

- PEEP (for spontaneous breaths), or
- PRESSURE SUPPORT plus PEEP (for pressure-supported breaths).

For spontaneous or pressure-supported breaths the Pressure Logic drops its flow message to zero once delivered flow drops to approximately 30% of the peak inspiratory flow.

Pressure-Controlled Breaths

The flow delivery logic for a pressure-controlled breath is similar to that of a pressure-supported breath except that:

- The breath can be triggered by the machine or patient activity, and
- The end of inspiration is determined by the clinician-set INSPIRATORY TIME control rather than by a drop in flow.

Pressure Slope

The PRESSURE SLOPE control affects the rate at which the flow signal increases to its peak value. In essence it operates through the Pressure Logic to determine how fast the FCV opens. Thus it affects how slowly or rapidly the preset inspiratory pressure level is achieved at the airway.

Flow and Volume Augmentation

The goals of flow and volume augmentation are to:

1. Ensure that the patient is never starved of flow, and
2. Reduce stacking of volume breaths (auto-cycling).

To achieve these goals, delivered flows must meet or exceed patient demand. To begin with, the Volume Logic begins to deliver a volume-controlled breath according to the clinician-selected PEAK FLOW, WAVEFORM, and TIDAL VOLUME

settings. Then, if the patient demands more flow than that delivered by the Volume Logic, proximal airway pressure drops. When pressure drops below baseline, the Pressure Logic sends a signal to increase flow beyond the flow signal from the Volume Logic to maintain airway pressure at baseline. This increase in flow is termed "flow augmentation."

If the patient continues to demand flow even after the clinician-set TIDAL VOLUME has been delivered, the Volume Logic will start sending a "zero flow" signal to the "Comparison" Logic. However, the Pressure Logic will continue to request flow to meet patient demand and to maintain pressure at baseline. The "Comparison" Logic, as usual, chooses the larger of these two flow signals (that from the Pressure Logic) and sends the flow signal to the FCV. When patient demand for flow drops to approximately 30% of its peak value, the Pressure Logic switches to a "zero flow" signal, and the FCV stops delivering flow. The patient receives a larger tidal volume than set on the controls because the patient has demanded a larger volume. The increase in tidal volume is termed "volume augmentation."

Volume-controlled breaths are illustrated in Figure 8-6. Flow and pressure curves show the impact of flow and volume augmentation capabilities.

Pressure Augmentation

Pressure augmentation provides additional pressure support beyond that provided by flow augmentation. Accordingly, with pressure augmentation, the patient is likely to perform even less work during a volume-controlled breath.

The flow delivery logic behind pressure augmentation is similar to flow augmentation except that the Pressure Logic ensures that proximal airway pressure never drops below the sum of:

$$(PEEP + \text{INSPIRATORY PRESSURE})$$

Accordingly, relative to flow augmentation, pressure augmentation causes the Pressure Logic to increase flow higher, thereby further unloading the active patient's ventilatory muscles.

Leak Makeup

A "leak" in the patient circuit can cause baseline pressures to drop. The Pressure Logic recognizes the drop in proximal airway pressure and sends a signal to the FCV (through the "Comparison" Logic) to increase flow until the proximal airway pressure returns to the PEEP level. This process is termed "leak makeup."

A "Disconnect" at the patient "wye" will elicit the same response from the pressure logic and FCV as previously described. Airflow through the patient circuit during disconnect would be a normal response.

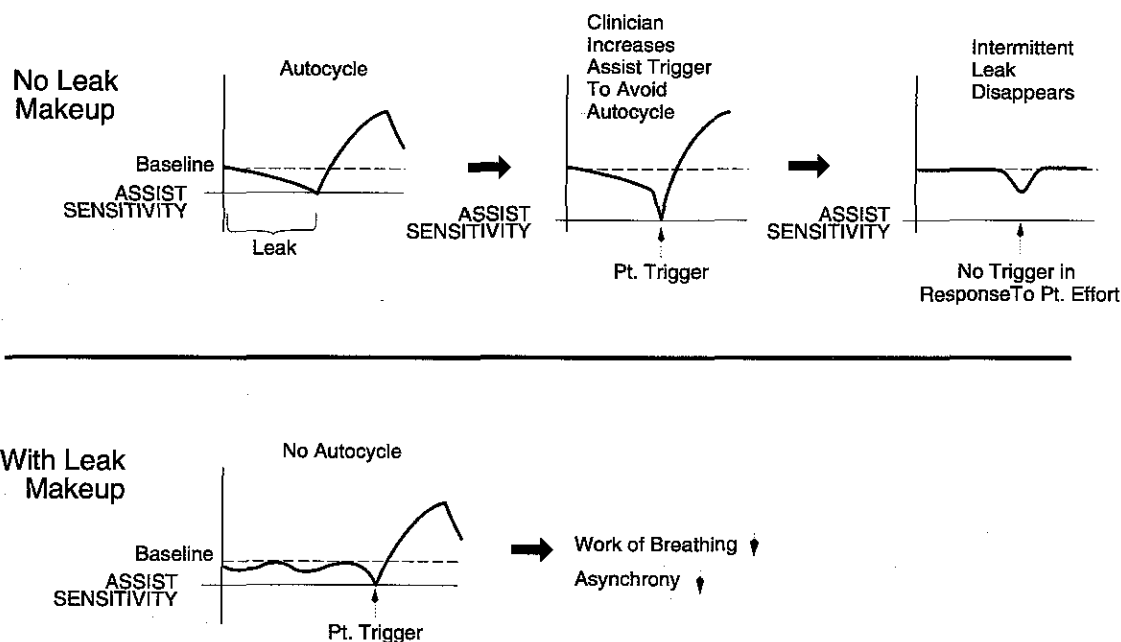
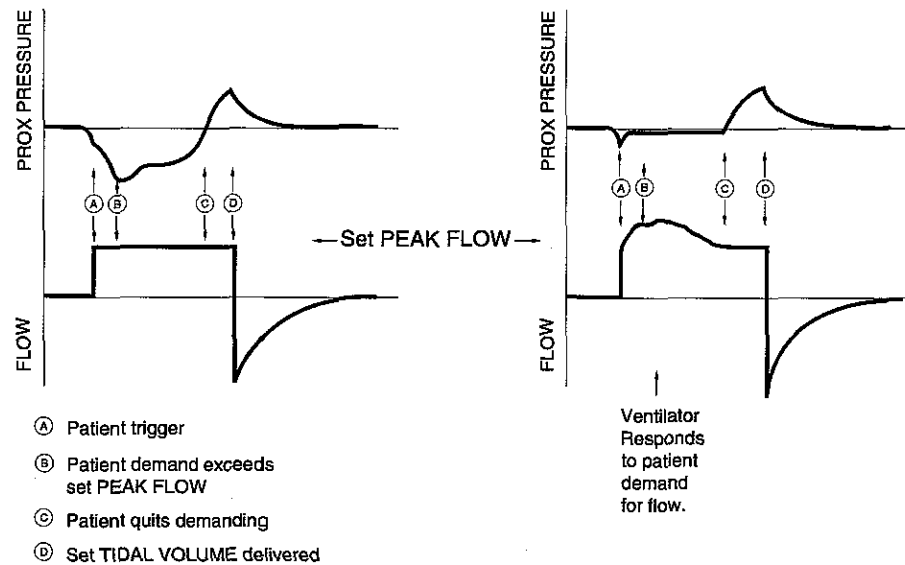


Figure 8-5 • Leak Makeup

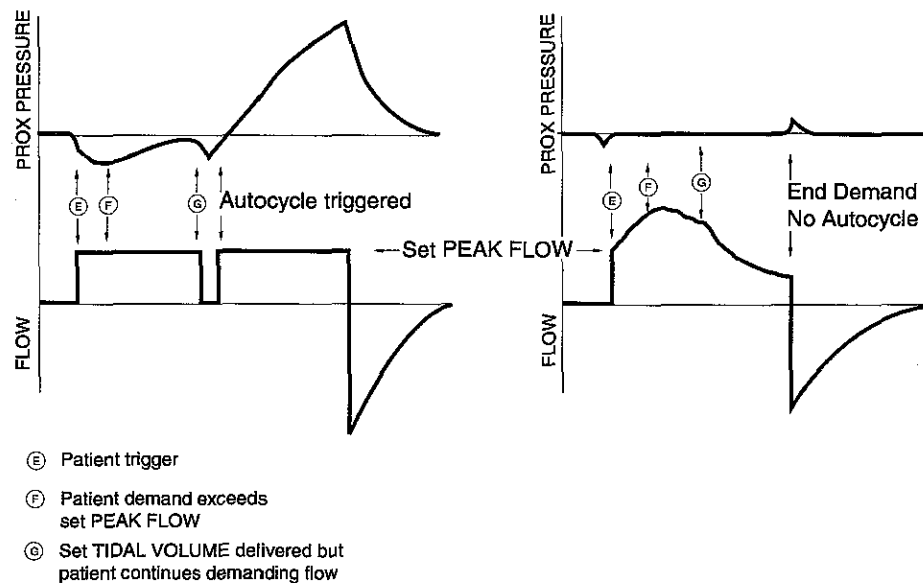
NO AUGMENTATION CAPABILITY

WITH AUGMENTATION CAPABILITY

EXAMPLE 1: Patient demands extra flow.



EXAMPLE 2: Patient demands both extra flow and extra volume.



FLOW & VOLUME AUGMENTATION

Figure 8-6 • Augmentation Graphs

RS-232 PROTOCOL

The following specifies the hardware and software protocol for the RS-232 digital communication port. Sufficient detail is provided to support most computer needs.

RS-232 PROTOCOL**HARDWARE**

Connector: Female 9-pin DSub connector (PC-AT serial port).

Duplex: Full

Baud Rate: 1200, 2400, 9600, 19200

Data: 8-bit character

1 Start bit

1 Stop bit

No Parity bit

Pin Assignment: EIA RS-232-C, Ventilator is DTE

The ventilator is DTE and interfaces to any DCE device through a cable wired 1-1.

DTE Name	DTE Pin	Direction	DCE Pin
DCD	1	<<-----	1 Not Used
RxD	2	<<-----	2
TxD	3	----->>	3
DTR	4	----->>	4
GND	5	-----	5
DSR	6	<<-----	6 Not Used
RTS	7	----->>	7 Tied High
CTS	8	<<-----	8
RI	9	<<-----	9 Not Used

Where: DCD—Data Carrier Detect
 RxD—Receive Data
 TxD—Transmit Data
 DTR—Data Terminal Ready
 GND—Ground
 DSR—Data Set Ready
 RTS—Request To Send
 CTS—Clear To Send
 RI—Ring Indicator

The ventilator can be interfaced to a DTE device with the following "null-modem" interface:

DTE Name	DTE Pin	Direction	DTE Pin	DTE NAME
GND	5	-----	5	GND
RxD	2	<<-----	3	TxD
TxD	3	----->>	2	RxD
DCD	1	<<-----	7	RTS
RTS	7	----->>	1	DCD
DTR	4	----->>	6 & 8	DSR & CTS
DSR & CTS	6 & 8	<<-----	4	DTR
RI	9	Not Used	9	RI

SOFTWARE

The ventilator's RS-232 port has two modes of communication. The first mode continuously outputs real time data every 10-msec. The second mode provides non-real time data upon request from an external computer. The modes can be selected in the Operator Diagnostics by way of baud rate selection.

Continuous Output (Default Mode)

The continuous output mode communicates at 19.2 Kbaud and sends out the real time data, (flow, pressure, breath phase (inspiration vs. exhalation), breath type, and alarm status) every 10-msec. Upon request, non-real time data will also be sent, however, it may delay the real time data by up to 25 msec. Note, the real time data is queued by the ventilator so that it is only delayed and not lost.

Data by Request.

All non-real time data (control settings, alarm settings/status, and monitor status) is provided upon request from an external device. This data can be requested at any baud rate, however at 19.2 Kbaud real time data is also transmitted.

DATA FORMAT

The ventilator receives and sends messages in variable length data packets. All packets are preceded by a SYN character, and terminated by a check sum.

The SYN character enables the receiver to detect the start of a message; therefore it is an illegal character within a data packet. If the binary value of SYN (16h) or DLE (10h) appears in the data packet (including the checksum), an escape sequence is used. The illegal character is preceded by the DLE character, and 10h is subtracted from its ordinal value.

Message Request Received by the Ventilator:

[SYN] [ID] [Check]

[SYN]: 16h

[ID]: 20h	Send All Control Settings
40h	Send All Alarm Settings/Status
60h	Send All Monitored Data

[Check]: Check Sum (The one's complement of the sum of all data contained in the data packet excluding the "SYN" and "CHECK" characters. This is the same as the sum of all functional or usable data that is actually transmitted.)

Messages Transmitted by the Ventilator

[SYN] [ID] [Data #1] ... [Data #n] [Check]

[SYN]: 16h

[ID]: 00h..0Fh	Real Time Data, No Alarms
10h 1Fh	Real Time Data, Alarm Condition
20h 3Fh	Control Settings
40h 5Fh	Alarm Settings
60h 7Fh	Monitor Settings

[Data #x]: Binary Data

[Check]: Check Sum

Real Time Data

Mode: Continuously, every 10-msec

Length: 6 bytes

Format: [SYN] [ID] [Data #1] ... [Data #3] [Check]

[ID]:

Bit 7 - 0	
Bit 6 - 0	
Bit 5 - 0	
Bit 4 - x	Alarm Condition
Bit 3 - y	Breath Type
Bit 2 - y	
Bit 1 - y	Breath Phase (Inspiration vs. Exhalation)
Bit 0 - z	

Alarm Condition:

0 - No Alarm

1 - Alarm

Breath Type:

000 - Volume

001 - Spontaneous

010 - Pressure Control

011 - Pressure-Support

100 - Reserved

101 - Reserved

110 - Reserved

111 - Reserved

Breath Phase:

0 - Inspiration

1 - Exhalation

[Data #1]	[Data #2]	[Data #3]:
xxxxxxx	xxxxyyy	yyyyyyy

x : Flow - 13 bits

Range: -300 to +300 LPM

Binary Scale: 1 bit = 0.1 LPM

Binary Range: 0 to 6000

Zero Off Set: 3000

y : Pressure - 11 bits

Range: -60 to +140 cmH₂OBinary Scale: 1 bit = 0.1 cmH₂O

Binary Range: 0 to 2000

Zero Off Set: 600

Control Settings

Mode: Upon Request

Length: 16 bytes

Format:

[SYN] [ID] [Data #1] ... [Data#13] [Check]

[ID]: 20h

[Data #1] Mode/Wave: Bit 7 - x)
 Bit 6 - x Mode
 Bit 5 - x)
 Bit 4 - y Wave
 Bit 3 - y Wave
 Bit 2 - Reserved
 Bit 1 - Reserved
 Bit 0 - Reserved

Mode: 000 - Assist Control
 001 - SIMV/CPAP(PSV)
 010 - Pressure Control
 011 - Reserved
 : :
 111 - Reserved

Wave: 00 - Square
 01 - Sine
 10 - Decelerating
 11 - Reserved

[Data #2] Switches: Bit 7 100% O₂ (1=on,0=off)
 Bit 6 Sighs On (1=on,0=off)
 Bit 5 Pres Aug (1=on,0=off)
 Bit 4 Nebulizer(1=on,0=off)
 Bit 3 Reserved (0)
 Bit 2 Reserved (0)
 Bit 1 Reserved (0)
 Bit 0 Reserved (0)

[Data #n]	Parameter	Range	Binary Scale	Binary Range
[Data #3]	Tidal Volume	0.03–2.00 L	0.01 L	1–200
[Data #4]	Rate	0–120 BPM	0.5 BPM	0–240
[Data #5]	Peak Flow	5–150 LPM	1 LPM	5–150
[Data #6]	Percent O ₂	21–100 %O ₂	1 %O ₂	21–100
[Data #7]	Assist Sensitivity	0.2–5.0 cmH ₂ O	0.1 cmH ₂ O	2–50
[Data #8]	Pressure Support	0–80 cmH ₂ O	1 cmH ₂ O	0–80
[Data #9]	Inspiratory Pause	0.0–2.0 sec	0.1 sec	0–20
[Data #10]	MMV	0–50 L	1 liter	0–50
[Data #11]	Inspiratory Time	0.0–5.0 sec	0.1 sec	0–50
[Data #12]	Compliance Comp	0.0–7.5 ml/cmH ₂ O	0.1 ml/cmH ₂ O	0–75
[Data #13]	Pressure Slope	P–9 to P9, –9 to 9	1	1–38

Alarm Settings/Status

Mode: Upon Request

Length: 14 bytes

Format:

[SYN] [ID] [Data #1] ... [Data#11] [Check]

[ID]: 40h

[Data #1]: Alarm Status Byte-1

- Bit 7—High Min Vol (1=on,0=off)
- Bit 6—Low Min Vol (1=on,0=off)
- Bit 5—High Insp Pres (1=on,0=off)
- Bit 4—Low Insp Pres (1=on,0=off)
- Bit 3—High Base Pres (1=on,0=off)
- Bit 2—Low Base Pres (1=on,0=off)
- Bit 1—High Rate (1=on,0=off)
- Bit 0—Low Rate (1=on,0=off)

[Data #2]: Alarm Status Byte-2

- Bit 7—I:E Limit (1=on,0=off)
- Bit 6—Run Diagnostics (1=on,0=off)
- Bit 5—Gas Fail (1=on,0=off)
- Bit 4—Failed To Cycle (1=on,0=off)
- Bit 3—Reserved (0)
- Bit 2—Reserved (0)
- Bit 1—Reserved (0)
- Bit 0—Alarm Silence (1=on,0=off)

[Data #n]	Parameter	Range	Binary Scale	Binary Range
[Data #3]	High Min Vol	0–80 L	1 L	0–80
[Data #4]	Low Min Vol	0–50 L	1 L	0–50
[Data #5]	High Insp Pres	0–120 cmH ₂ O	1 cmH ₂ O	0–120
[Data #6]	Low Insp Pres	3–99 cmH ₂ O	1 cmH ₂ O	3–99
[Data #7]	High Base Pres	0–55 cmH ₂ O	1 cmH ₂ O	0–55
[Data #8]	Low Base Pres	0–50 cmH ₂ O	1 cmH ₂ O	0–50
[Data #9]	High Rate	0–155 BPM	1 BPM	0–155
[Data #10]	Low Rate	3–99 BPM	1 BPM	3–99
[Data #11]	I:E Override	on/off	n/a	1/0

Monitor Status

Mode: Upon Request

Length: 18 bytes

Format:

[SYN] [ID] [Data #1] ... [Data#15] [Check]

[ID]: 60h

[Data #1]: Bit 7—Control Breath (1=on,0=off)
 Bit 6—Sigh Breath (1=on,0=off)
 Bit 5—Patient Effort (1=on,0=off)
 Bit 4—MMV Active (1=on,0=off)
 Bit 3—Reserved
 Bit 2—Reserved
 Bit 1—Reserved
 Bit 0—Reserved

[Data #n]	Parameter	Range	Binary Scale	Binary Range
[Data #2]	MSB Tidal Vol	0–9.99 L	0.01 L	0–999
[Data #3]	LSB " "			
[Data #4]	MSB Total Min Vol	0–99.9 L	0.1 L	0–999
[Data #5]	LSB " "			
[Data #6]	MSB Spont Min Vol	0–99.9 L	0.1 L	0–999
[Data #7]	LSB " "			
[Data #8]	MSB I:E Ratio	0.00–4.0	0.01	0–400
[Data #9]	LSB " "			
[Data #10]	Total Rate	0–155 BPM	1 BPM	0–155
[Data #11]	Spont Rate	0–155 BPM	1 BPM	0–155
[Data #12]	MMV %	0–100 %/hr	1 %/hr	0–100
[Data #13]	Mean Pres	0–140 cmH ₂ O	1 cmH ₂ O	0–140
[Data #14]	Peak Pres	0–140 cmH ₂ O	1 cmH ₂ O	0–140
[Data #15]	Plateau Pres	0–140 cmH ₂ O	1 cmH ₂ O	0–140

MSB stands for Most Significant Byte

LSB stands for Least Significant Byte

9. PARTS & ACCESSORIES

Parts Ordering.....9-2 to 9-6

PARTS ORDERING

VENTILATOR BASIC ACCESSORY KIT

To obtain BEAR® 1000 Ventilator parts, contact customer service.

The BEAR® 1000 Ventilator comes with a Basic Accessory Kit (P/N 50-08600-00) which includes the following:

1. DISS Air Hose, 12 feet.....P/N 50000-01000
2. DISS O2 Hose, 12 feet P/N 50000-01001
3. Flexible Circuit Support Arm P/N 52000-30100
4. Circuit Tube Hanger Clip
(available in multipacks of 6) P/N 50000-03099
5. Rail Clamp Bracket for Support Arm.....P/N 52000-30101
6. Proximal Line Bacteria Filter P/N 50000-01106
7. Mainflow Bacteria Filter with Coupler P/N 50000-01054
8. 3/4" Tubing, 14 inches P/N 52000-00328
9. Condensate trap
(available in multipacks of 3) P/N 50000-09901
10. Flow Sensor P/N 50000-09900
11. Instruction Manual.....P/N 50-10613-00

VENTILATOR MOUNTING OPTIONS

The BEAR® 1000 Ventilator can be mounted as follows:

1. BEAR® 1000 Cart,
(with 120V 60Hz outlet) P/N 51000-08781
2. BEAR® 1000 Cart,
(with power outlet) P/N 51000-08951
3. BEAR® 1000 Ventilator Compressor
(120V 60Hz).....P/N 50-08950-00
4. BEAR® 1000 Ventilator Compressor
(220V 50Hz).....P/N 50-08950-02

NOTE: Other voltages available.

STARTER KITS

1. Accessory Starter Kit P/N 50000-08611

The starter kit includes the following parts:

- Flow Sensor (2) P/N 50000-09900
Exhalation Diaphragm (Multipack of 3).....P/N 50000-08610

2. Advanced Accessory Starter Kit.....P/N 50000-08612

the advanced kit includes the following parts:

- Flow Sensor (2) P/N 50000-09900

Exhalation Diaphragm (6)

(available as a multipak of 3) P/N 50000-08610

Exhalation Manifold (1) P/N 51000-08591

Diaphragm Mounting Base, O-ring (1)

(available as a multipak of 3) P/N 50000-08607

Condensate Trap

(available as a multipak of 3) P/N 50000-09901

Diaphragm Mounting Base (1).....P/N 51000-08580

The Exhalation Valve Assembly (P/N 50000-08602) includes the following parts:

1. Diaphragm Mounting Base O-ring
(O-ring available in a multipack of 3).....P/N 50000-08607

2. Exhalation Diaphragm
(available as a multipack of 3) P/N 50000-08610

3. Exhalation Manifold.....P/N 51000-08591

4. Condensate Jar
(Available as a mulitpack of 3).....P/N 50000-09901

**EXHALATION VALVE
ASSEMBLY**

**MISCELLANEOUS
PARTS**

The following list includes all the parts a clinician may eventually desire:

1. Fuse Set, 3 pairs 120 V/60 Hz P/N 50-08603-00
2. Fuse Set, Ventilator pair 120 V/60 Hz P/N 50-08604-00
3. Fuse Set, Humidifier pair 120 V/60 Hz.....P/N 50-08605-00
4. Fuse Set, Graphic Display pair
120 V/60 Hz P/N 50-08606-00
5. Flow Sensor P/N 50000-09900
6. Fan Filter Pad (2 required) P/N 51000-08655
7. Maintenance Manual P/N 50000-12131
8. Air/O₂ Inlet Water Trap Bowl.....P/N 52000-01144
9. Air/O₂ Inlet Water Trap Filter P/N 52000-01145
10. Exhalation Manifold/Contamination
Trap Assembly P/N 50000-10077
11. BEAR® 1000 VarFlex® Flow
Sensor Silicone Adapter.....P/N 50000-09905
12. BEAR® 1000 VarFlex® Flow
Sensor Purge Adapter Assembly P/N 50000-09906

UPGRADE OPTIONS

The following upgrade options for the BEAR® 1000 Ventilator are available:

1. BEAR® Graphic Display P/N 50000-20001

REUSABLE CIRCUITS

Two adult reusable circuits are available. They are identical except with regard to the length of the tubing. One circuit offers 48" tubes while the other offers 72" tubes.

Reusable Adult Circuit Kit, 48" P/N 50000-08608
(Includes*)

Reusable Adult Circuit Kit, 72" P/N 50000-08609
(Includes†)

1. *†Tubing, 1/4" ID (6 feet).....P/N 50000-03037
2. *†Patient Wye with Prox Fitting P/N 51000-01104
3. *†Patient Wye with Prox & Temp Port
Fittings.....P/N 51000-01105
4. *†Tubing, 14" x 3/4" P/N 52000-00328
5. *Adult Circuit Tubing, 48" (2 each) P/N 51000-02742
6. †Adult Circuit Tubing, 72" (2 each).....P/N 51000-02759

A pediatric reusable circuit is also available as P/N 50000-01145, which includes:

1. Tube Connectors, Infant (3 each)
(available as a multipack of 6) P/N 50000-03101
2. Mainflow Bacteria Filter, Infant.....P/N 50000-01056
3. Adapter, Infant Temp Probe (1 each)
(available as a multipack of 6) P/N 50000-03108
4. Connector, 3/8" OD, both ends (2 each)
(Available as a multipack of 6).....P/N 50000-03064
5. Flexible hose, corrugated (2 each)
(Available as a multipack of 6).....P/N 50000-03058
6. Endotracheal Connector (1 each)
(available as a multipack of 3) P/N 50000-03061
7. Endotracheal Adapter, 11 mm ID/7 mm OD (1 each)
(available as a multipack of 6) P/N 50000-03072
8. Adapter, 15mm OD/9 mm OD (1 each)
(available as a multipack of 6) P/N 50000-03060
9. Tapered Flextube.....P/N 51000-08114
10. Tubing, 3/8" ID
(available in 25-foot length) P/N 50000-03039
11. Tubing, 1/4" ID
(available in 50-foot length) P/N 50000-03037

10. UPDATES

This section of the BEAR® 1000 Ventilator manual is provided for your convenience to insert instruction sheets for ventilator updates/enhancements and for clinical application bulletins pertaining to this ventilator.

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